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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,310	08/31/1999	KOJI UKAI	425-736P	2449

2292 7590 01/27/2004

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,310

Applicant(s)

UKAI ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-11,13-18,20-23,25,26,28-30 and 33-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-11,13-18,20-23,25,26,28-30 and 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendments and Request for Continued Examination filed 11/25/03 is acknowledged.

Note: Claims appear to contain numerous typographical errors, for example the names of the medicinal substances. Corrections are required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6-10, 13-17, 20-22, 25, 28-30, 39 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al (JP 07267850).

Aoki teaches a method of preventing the unpleasant taste of a medicine by providing a composition containing the medicine with the unpleasant taste, a water-soluble polymer and a waxy substance. The medicine can be any unpleasant pharmaceutical agent such as azelastine (an antiallergic agent), erythromycin and chloramphenicol (antibiotics), Phenobarbital, diltiazem hydrochloride, etc (see pages 1 and 2 of translation).

Aoki teaches that the medicine constitutes from 1 to 50% by weight and the polymer constitutes from 5 to 60% by weight of the composition. Also Aoki teaches that the polymers are selected from the group consisting of cellulose, gelatin, carrageenan,

casein, etc (see page 2, lines 12-16 and claim 5). The formulations can be in the form of granules, powder, dry syrup, tablets, etc (see abstract and claim 10).

Aoki teaches the method of preparing the composition which includes **mixing** of the medicinal component with the wax substance and the water-soluble polymer (see page 2, item 0013, claims 1 and 11).

Claims 1-3, 7-10, 13-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Drug Information on Vantin®, by Pharmacia /& Upjohn (obtained through on-line PDR).

Pharmacia /& Upjohn in the Drug Information on Vantin® discloses that the antibiotic medication, also known as cefpodoxime proxetil, is available in both tablet form and powder for suspension. It discloses that each 5 ml of Vantin® oral suspension contains cefpodoxime proxetil equivalent to 50 mg or 100 mg of cefpodoxime activity after constitution and contains additives such as artificial flavorings, BHA, carrageenan, citric acid, etc (see page 2, lines 2-7).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 11, 18, 23, 26, 29-30, 33-38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki in view of Matoba et al (5,464,612).

Aoki, discussed above, lacks specific teachings on preventing the unpleasant taste of donepezil hydrochloride.

Matoba teaches a solid preparation characterized by an effective mitigation of the bitterness or other unpleasant taste and/or odor of an active ingredient. The medicinally active ingredients having an unpleasant taste and/or odor may frequently have a basic group. The basic groups are such as a nitrogen-containing heterocyclic group such as piperidyl. Medicinally active agents having a bitter taste are such as antibiotics such as cefpodoxime, cerebral circulation improving agents, central nervous system drugs and psychotropic agents (col. 4, lines 1-63).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted donepezil hydrochloride for other medicinal agents taught by Aoki, because donepezil hydrochloride, being a basic medication, has a bitter taste as taught by Matoba, and it would be a logical extension of the combined references to have included donepezil hydrochloride in a composition preventing the bitter taste, and because of widening the scope of medications treated to prevent their unpleasant taste.

Response to Arguments

Applicant's arguments filed 11/25/03 have been fully considered but they are not persuasive.

Applicant argues that Aoki (JP '850) teaches a mixture of a medicine with a water-soluble polymer and wax, and fails to teach the interaction of the basic medicine with an acidic polysaccharide as instantly claimed. Applicant further argues that the present invention does not use wax as required by the JP '850 reference (see pages 17,18 and 20).

This is not commensurate with the scope of the claims because most of the rejected claims are "composition claims" which comprise a number of ingredients. All of these limitations are clearly met by Aoki's reference. The method claims require a step of "blending or mixing an anionic polymer with the basic medicine". Aoki reads " the ingredients can be mixed with each other". Generally "mixing" and "blending" are interchangeable terminologies. Again Aoki's reference meets the required limitations of the said claims.

Applicant argues that Matoba discloses a clad powdery or granular preparation of medicinally active ingredients having a bitter taste. However Matoba was considered a supportive evidence that basic medicines are known to have bitter (unpleasant) taste.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Aoki is shown to

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teach the formulations and method of preparing the formulations and Matoba is supporting the known fact that basic medicines are bitter and need masking of bitterness.

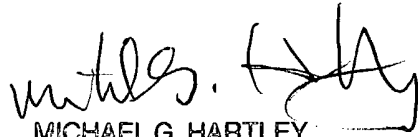
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghigatian whose telephone number is 703-308-6330 (effective February 04, 2004 the telephone number will be 571-272-0615). The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927 (effective February 04, 2004 the telephone number will be 571-272-0602). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghigatian
January 22, 2004


MICHAEL G. HARTLEY
PRIMARY EXAMINER